K110250

510(k) SUMMARY

OCT 14 2011

MPXX™ POWDER FREE NATURAL RUBBER LATEX EXAMINATION GLOVES

Submitter's Name	TOTAL GLOVE COMPANY SDN. BHD.
Submitter's Address	Lot 2584, Jalan Perusahaan 3, Kamunting Industrial Estate 34600 Taiping, Perak, Malaysia
Submitter's Phone Number	605-8295 512
Submitter's Fax Number	605-8915 500
Name of Contact Person	Ooi Loon Seng
Date of Preparation	06 October 2011
Name of Device Trade Name : Common Name : Classification Name :	 MPXX™ POWDER FREE NATURAL RUBBER LATEX EXAMINATION GLOVES Latex Examination Gloves Patient Examination Gloves
Legally Marketed Device to which Equivalency is Being Claimed	MPXX™ Powder Free Natural Rubber Latex Examination Gloves as described in this 510 K Notification is substantially equivalent to K981767, Qtexx Powder-Free Latex Examination Gloves with 50 Micrograms or Less of Total Water Extractable Protein Per Gram which is the current Class 1 Patient Examination Glove bearing the product code 80LYY (21 CFR 880.6250). It meets all the current specifications listed under the ASTM Specification D 3578-05, Standard Specification for Rubber Examination Gloves.

Description of the Device	MPXX™ Powder Free Natural Rubber Latex Examination Gloves are substantially equivalent to the Class 1 patient examination glove bearing the product code 80LYY (21 CFR 880.6250). It meets all the current specifications listed under the ASTM Specification D-3578-05, Standard Specification for Rubber Examination Gloves. They are made from natural rubber latex. They are natural white in color and are powder free.
Intended Use of the Device	MPXX™ Powder Free Natural Rubber Latex Examination Gloves are intended for single use for medical purposes that is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personnel and the patient.
Summary of Technological Characteristic Compared to the Predicate Device	There is no different technological characteristic. Gloves are made from natural rubber latex compound and the initial products are low powdered natural rubber latex gloves. These gloves are using the existing technology, i.e. multiple washing and rinsing processes.
Brief Description of Non-Clinical Tests	Testing were performed per ASTM D 3578-05, Standard Specification for Rubber Examination Gloves and 21 CFR 800.20. Gloves meet all the current ASTM D 3578-05 requirements. Primary skin irritation testing in the rabbit and delayed contact sensitization testing in the guinea pig indicate no irritation or sensitization. Final product has been tested negative for the presence of starch using the USP iodine test.
Brief description of Clinical Tests	No new clinical tests were conducted under this 510(k).
Conclusions Drawn from the Non-Clinical and Clinical Tests	Non-Clinical laboratory and animal based test data indicate that the powder free product meets all performance and biocompatibility requirements.
Other Information Deemed Necessary by FDA	Not Applicable.

Substantial Equivalence Comparison Table

Characteristics and Parameters	Subject Device MPXX™ Powder Free Natural Rubber Latex Examination Gloves	Predicate Device Qtexx Powder-Free Latex Examination Gloves with 50 Micrograms or Less of Total Water Extractable Protein Per Gram (K981767)	Substantial Equivalence (SE)
Product Code	80LYY	80LYY	
Intended Use	MPXX™ Powder Free Natural Rubber Examination Gloves is a single use device intended for medical purposes that is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personnel and the patient.	Qtexx Powder-Free Latex Examination Gloves with 50 Micrograms or Less of Total Water Extractable Protein Per Gram is a single use device intended for medical purposes that is worn on the hand of health care and similar personnel to prevent contamination between the health care personnel and the patient.	Yes, Substantial Equivalence
Glove Thickness and Length	Meets ASTM D 3578-05: -Palm Thickness of ≥ 0.08mm -Finger Thickness ≥ 0.08mm -Length ≥ 240mm	Meets ASTM D 3578-95: -Palm Thickness of ≥ 0.08mm -Finger Thickness ≥ 0.08mm -Length ≥ 230mm	Yes, Substantial Equivalence
Tensile Strength	Meets ASTM D 3578-05: - Tensile Strength ≥ 18MPa (≥ 18MPa per Standard) - Elongation ≥ 650%	Meets ASTM D 3578-95: - Tensile Strength ≥ 14MPa (≥ 14MPa per Standard) - Elongation ≥ 700%	Yes, Substantial Equivalence
Freedom from Holes	Meets Requirements per 21CFR800.20: Gloves Free of Holes at quality level of AQL 1.5 (AQL 2.5 required per standard)	Meets Requirements per 21CFR800.20: Gloves Free of Holes at quality level of AQL 1.5 (AQL 2.5 required per standard)	Yes, Identical
Materials	Natural Rubber Latex	Natural Rubber Latex	Yes, Substantial Equivalence
Color	Natural Color	Natural Color	Yes, Identical
Biocompatibility	Passes: - Primary Skin Irritation - Dermal Sensitization	Passes: - Primary Skin Irritation - Dermal Sensitization	Yes, Identical
Powder Free	Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Yes, Identical

Protein Content	Meets Applicable Definition for Protein Content; ≤ max 50 (ug/dm^2)	Meets Applicable Definition for Protein Content; ≤ max 50 (ug/dm^2)	Yes, Identical
Sterility	Not applicable: Non-sterile	Not applicable: Non-sterile	Yes, Identical

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 14 2011

Total Gloves, SDN BHD
C/O Ms. Ooi Loon Seng
Regulatory Affairs Manager
Lot 2584, Jalan Perusahaan 3, Kamunting Industrial Estate
Taipang City, Perak Province
MALAYSIA 34600

Re: K110250
Trade/Device Name: MPXX™ Powder-Free Natural Rubber Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: September 12, 2011
Received: September 16, 2011

Dear Ms. Seng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

K110250

Applicant	:	TOTAL GLOVE COMPANY SDN. BHD. Lot 2584, Jalan Perusahaan 3, Kamunting Industrial Estate, 34600 Kamunting , Perak, Malaysia.
510(k) Number (if known)	:	K110250 *
Device Name	:	MPXX™ Powder Free Natural Rubber Latex Examination Gloves
Indications For Use	:	

MPXX™ Powder Free Natural Rubber Latex Examination Gloves are intended for single use for medical purposes that is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personnel and the patient.

(Division Sign-Off) Concurrence of CDRH Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110250

Prescription Use _____ OR Over-The-Counter X
Per 21 CFR 801.109